and the time point of stability of, the procedure. FDA will conditionally approve, however, a study at this time of LASIK enhancement in 25 subjects previously treated with your laser; please see the conditions of approval below. Requests for additional subjects for enhancements for prior clinical patients will be evaluated as additional data is submitted to support stability of the procedure. If you agree to conduct your investigation within the modified limit, you may implement that change at the institution enrolled in your investigation where you have obtained institutional review board (IRB) approval. If you do not agree to this modified limit, you should consider this letter as a disapproval of your request for an expansion of the investigation, and you have an opportunity to request a regulatory hearing as described in the enclosure "Procedures to Request a Regulatory Hearing."

We regret to inform you that your request to study simultaneous bilateral LASIK treatment is disapproved and you may not implement the expansion of your investigation. Our disapproval is based on the following deficiency:

> If you wish to study simultaneous bilateral LASIK surgery, you should propose a substudy comparing simultaneous with sequential treatment to establish the safety of the simultaneous procedure. Your substudy should contain satisfactory preliminary data on the safety, effectiveness and stability of the procedure on the primary eyes. In your substudy you should specify the time between surgeries for each eye and any criteria used to determine when to treat the fellow eye; time between surgeries and treatment criteria should be specified for both simultaneous and sequential procedures.

If you submit information correcting the deficiency, FDA will reevaluate the proposed expansion of the investigation. Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE supplement. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.

Also, FDA acknowledges the telephone conversation between you and Dr. Beers of the FDA on August 25, 1997 in which you were granted permission to perform simultaneous bilateral surgery on two subjects because of pressing personal needs of the subjects.

Your response to FDA conditional approval letter of August 7, 1997, remains conditionally approved because you adequately addressed only deficiencies 1, 2, 3, 4, 6, 7a, 8, 9, 10, and 11. You may continue your investigation at the institution where you have obtained IRB approval and submitted certification of IRB approval to FDA. Your investigation is limited to 1 institution and 150 total subjects: 100 subjects for low myopia (from -0.5 to -6.75 D); 25 subjects for high myopia (from -7.00 to -15 D), and 25 subjects for enhancements of prior clinical patients.